

Certificate of Analysis

FBS Analog

FBS Performance Alternative
Bovine Calf Serum
Sterile filtered

Country of Origin USA
Processed in USA

Lot/Batch Number: 280A14

Catalog Number: FBSA-US-1L

Expiration Date: November 2025

Store at: -10°C to -20°C

Date of CoA: 13.11.2020

Tel: +49-8565-964961

Fax: +49-8565-964963

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HRB 7285

Amtsgericht Landshut

Tax-No: 141/122/45600

VAT-No: DE 256339221



1) Physical, Chemical and Protein Analysis:

| Test | Method | Specifications | Result | Units |
|---------------|---------------------|-----------------|--------|----------|
| Albumin | Vet Test Kit | Test and Report | 3.7 | g/dL |
| Alpha 1 | Cellulose Acetate | Test and Report | 0.4 | g/dL |
| Alpha 2 | Cellulose Acetate | Test and Report | 0.8 | g/dL |
| Beta 1 | Cellulose Acetate | Test and Report | 1.0 | g/dL |
| Beta 2 | Cellulose Acetate | Test and Report | 0.4 | g/dL |
| Endotoxin | LAL Kinetic, USP 85 | Test and Report | < 2 | EU/ml |
| Gamma 1 & 2 | Cellulose Acetate | Test and Report | 0.6 | g/dl |
| Hemoglobin | Fleming & Woolf | Test and Report | 8.6 | mg/dl |
| Osmolality | USP 785 | Test and Report | 289 | mOsmo/kg |
| рН | USP 791 | Test and Report | 7.37 | n.a. |
| Total Protein | Biuret | Test and Report | 6.9 | g/dL |

2) Sterility and Virus Testing

| Test | Method | Specifications | Result | Units |
|---|-----------------------------|----------------|--------------|-------|
| Aerobic Bacteria | Current USP/EP 2.6.1 | not detected | not detected | n.a. |
| Anaerobic Bacteria | Current USP/EP 2.6.1 | not detected | not detected | n.a. |
| Fungi (Yeast & Mold) | Current USP/EP 2.6.1 | not detected | not detected | n.a. |
| Mycoplasma | Barile & Kern, Large Volume | not detected | not detected | n.a. |
| Bluetongue | 9 CFR 113.53c | negative | Negative | n.a. |
| Bovine Adenovirus | 9 CFR 113.53c | negative | Negative | n.a. |
| Bovine Parvovirus | 9 CFR 113.53c | negative | Negative | n.a. |
| Bovine Respiratory Syncytial Virus | 9 CFR 113.53c | negative | Negative | n.a. |
| Rabies | 9 CFR 113.53c | negative | Negative | n.a. |
| Reovirus | 9 CFR 113.53c | negative | Negative | n.a. |
| Cytopathogenic Agents (IBR) | 9 CFR 113.53c | negative | Negative | n.a. |
| Hemadsorbing Agents (PI 3) | 9 CFR 113.53c | negative | negative | n.a. |

3) Cell Culture

| Test | Method | Specifications | Result | Units |
|------------------------|-------------------------|----------------|--------|-------|
| Suspension Cells (CHO) | Growth Promotion | 90 – 119 | 100,7 | % |
| Adherent Cells | Growth Promotion | 90 – 119 | 132,9 | % |

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4) Biochemistry

| Test | Method | Specifications | Result | Units |
|------------------------------------|----------|-----------------|--------|--------|
| Alkaline Phosphatase | Vet Test | Test and Report | 202 | U/L |
| ALT (SGPT) | Vet Test | Test and Report | 12 | U/L |
| AST (SGOT) | Vet Test | Test and Report | 80 | U/L |
| Bilirubin (Total) | Vet Test | Test and Report | 0.4 | mg/dL |
| Calcium | Vet Test | Test and Report | 9.0 | mg/dL |
| Chloride | Vet Test | Test and Report | 101 | mEq/L |
| Cholesterol | Vet Test | Test and Report | 116 | mg/dL |
| Creatinine | Vet Test | Test and Report | 0.9 | mg/dL |
| Glucose | Vet Test | Test and Report | 135 | mg/dL |
| Iron | Vet Test | Test and Report | 615 | ug/dL |
| Lactate Dehydrogenase | Vet Test | Test and Report | 1147 | IU/L |
| Percent Saturation-Iron | Vet Test | Test and Report | 66 | % |
| Phosphorus | Vet Test | Test and Report | 9.2 | mg/dL |
| Potassium | Vet Test | Test and Report | 6.0 | mEq/L |
| Sodium | Vet Test | Test and Report | 144 | mEq/L |
| Total Iron binding Capacity | Vet Test | Test and Report | 929 | ug/dL |
| Triglyceride | Vet Test | Test and Report | 21 | mmol/l |
| Urea Nitrogen (BUN) | Vet Test | Test and Report | 8 | mg/dL |
| Uric Acid | Vet Test | Test and Report | 1.9 | mg/dL |

Product meets EU requirements for production of technical blood products.

This product was manufactured from bovine calf blood collected exclusively from approved harvest facilities. All bovine calf serum used in this product is derived from calves that are of United States origin and have passed ante- and post-mortem inspection. All harvest facilities are USDA inspected and located within the continental United States of America. All collection and processing activities are performed under the strict guidance of standard operating procedures.

This product was processed aseptically using 0.2 μ m filters as final filters. Filters are tested for integrity prior to sterilization and after use. This product was filled into sterile 1,000 ml jugs.

For in-vitro diagnostic, research and further manufacturing use only — Not for human or animal consumption

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Dr. Peter Haeusl Managing Director Biophyll GmbH